UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY LITIGATION	MDL Case No.13md2452 AJB (MDD) As to all related and member cases 1) ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT NOVO NORDISK, INC.'S MOTION TO DISQUALIFY DR. FLEMING AS AN EXPERT FOR PLAINTIFFS (Doc. No. 902) 2) ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISQUALIFY DR. FLEMING AS AN EXPERT FOR PLAINTIFFS (Doc. No. 908)

Presently before the Court are two motions to disqualify Dr. G. Alexander Fleming as an expert for Plaintiffs. (Doc. Nos. 902, 908.) On March 12, 2015, the motions were taken under submission following oral argument. After consideration of the parties' arguments, the Court **GRANTS IN PART** and **DENIES IN PART** both pending motions to disqualify Dr. Fleming and strike his expert report.

///

I. BACKGROUND[1]

This multi-district litigation involves claims for personal injuries and/or wrongful death allegedly caused by four types of incretin treatments prescribed for Type 2 diabetes. As part of phased discovery on issues of preemption and general causation, the parties exchanged expert reports on December 15, 2014. Plaintiffs served Defendants with the expert report of Dr. G. Alexander Fleming, who was designated as a preemption expert for Plaintiffs.[2] On January 16, 2015, Defendant Novo Nordisk, Inc. ("Novo") moved to disqualify Dr. Fleming as an expert for Plaintiffs and strike his expert report. (Doc. No. 902.) Novo's motion is predicated on Dr. Fleming's prior consulting relationship with Novo. (Doc. No. 925, p. 4.)[3] As an additional ground for disqualification, Novo argues that Dr. Fleming is a competitor as defined by the protective order, and that Plaintiffs improperly disclosed confidential discovery materials to Dr. Fleming without prior notice to Defendants. (*Id.* p. 23.) The remaining Defendants Merck Sharp & Dohme Corp., Eli Lilly and Company, and Amylin Pharmaceuticals, LLC, also filed a motion to disqualify Dr. Fleming based on Dr. Fleming's status as a competitor, and the alleged improper disclosure of confidential discovery materials to Dr. Fleming in violation of the protective order. (Doc. No. 908.) Plaintiffs oppose both motions. (Doc. No. 938.)

Although Plaintiffs and Novo characterize the nature and import of Dr. Fleming's consulting relationship with Novo differently, the parties acknowledge that Dr. Fleming served as a consultant to Novo for several years beginning in September 1999. Over the

---

[1] The relevant facts and each parties' characterization of those facts are detailed in the parties' briefing, (Doc. Nos. 908-1, 925, 942), and reiterated in large part in the transcript from the oral argument held on March 12, 2015 (Doc. No. 1000). Relevant facts are also stated in Dr. Fleming's declaration in opposition of disqualification. (Doc. No. 937-1.) Accordingly, the facts set forth herein are restated in summary form.

[2] Although currently designated as Plaintiffs' preemption expert, at oral argument counsel for Plaintiffs indicated that Dr. Fleming could also be designated as an expert for Plaintiffs on issues of general causation, specific causation, and endocrinology. (Doc. No. 1000, p. 6:4-24.)

[3] Novo's moving papers and Plaintiffs' opposition were each filed under seal on the docket. The parties also filed partial or redacted versions of the briefing, which are available publicly on the docket. This accounts for reference to varying docket numbers with respect to the same documents.

course of nearly ten years, Dr. Fleming entered into multiple agreements documenting his role as a consultant to Novo on a variety of matters. (Doc. No. 925, p. 7-8.) Each agreement contained confidentiality provisions that precluded Dr. Fleming from disclosing information obtained while working with Novo. (*Id.* at 9.)[4] During his tenure as a consultant to Novo, Dr. Fleming participated in advisory board meetings, as part of expert panels, and attended meetings on Novo's behalf. (Doc. No. 925, p. 9; Doc. No. 942, p. 5-6.) Dr. Fleming consulted with Novo regarding GLP-1 analogues generally, and on Victoza, one of the drugs at issue in the underlying litigation. (Doc. No. 925, p. 9; Doc. No. 942, p. 6.)

More specifically, Novo contends that during his time as a consultant for Novo Dr. Fleming regularly participated on high-level global advisory boards, viewed presentations, and heard discussions on many topics relevant to this litigation and to the opinions in Dr. Fleming's expert report. (Doc. No. 925, p. 9-10.) These topics included: clinical development strategy and objectives, analysis of pre-clinical and clinical study findings, evaluation of potential effects on beta-cell growth and proliferation, review of potential safety issues, including pancreatitis and cancer-related findings in rodents, plans for clinical trial and post-marketing study design, and strategy for addressing potential regulatory and labeling issues. (*Id.*) Novo's motion summarizes "key meetings" that Dr. Fleming attended while working for Novo. (*Id.* at 9-11.) Dr. Fleming also assisted Novo with the Investigational New Drug application ("IND"), New Drug Application ("NDA"), and fast-track drug applications for FDA approval of Victoza. (*Id.* at 11.)

Plaintiffs characterize Dr. Fleming's role differently. Accordingly to Plaintiffs, Dr. Fleming spent only 10-20% of his consulting time with Novo on Victoza specifically. (Doc. No. 942, p. 6.) Plaintiffs also contend that Dr. Fleming was not privy to large amounts of Novo documents or data and did not obtain information relevant to the issues in the underlying case. (*Id.*) Plaintiffs note that Dr. Fleming's work for Novo predates the

[4] The agreements are summarized in detail in Novo's motion to disqualify, (Doc. No. 925, p. 9), and attached to the declaration of Heidi Levine, (Doc. No. 902-1).

issues regarding pancreatic cancer that form the basis of the underlying litigation, and that Dr. Fleming has not consulted for Novo at all since 2010. (Doc. No. 937, ps. 6, 17.)

As relevant to the instant motions, Dr. Fleming co-founded a company called Exsulin in 2006. (*Id.* at 6.) Exsulin is currently developing a peptide-based drug targeted at regenerating the insulin-producing islets in patients with both Type 1 and Type 2 diabetes. (Doc. No. 925, p. 24-25.) Exsulin currently has a drug, also called Exsulin, in Phase II clinical trials. (*Id.*) Dr. Fleming serves as Chairman of Exsulin's Board of Directors and as its Chief Medical Officer. (*Id.*) Prior to forming Exsulin, Dr. Fleming co-founded Kinexum LLC and currently serves as that company's President and Chief Executive Officer. Kinexum LLC provides services and expertise supporting the advancement of new healthcare products towards commercialization.[5]

Prior to working as a private consultant, Dr. Fleming worked for the FDA as a Medical Officer in the Division of Metabolism and Endocrine Drug Products. Dr. Fleming also worked as the Supervisory Medical Officer for the FDA beginning in 1989. Dr. Fleming held this position until he retired from the FDA as its senior endocrinologist in 1998. While at the FDA, Dr. Fleming had a variety of responsibilities, including regulation of diabetes and other metabolic drugs, working as the head of clinical reviewers of endocrine and metabolic treatments, and representing the FDA at international initiatives.

Dr. Fleming's expert report includes discussions of the FDA approval process for new drugs, the FDA regulatory history for the incretin mimetics at issue in this litigation, and an overview of the FDA process for label changes by the Changes Being Effected ("CBE") process. The report also includes drug-specific analyses and discussions of various studies implemented by Defendants.

///

///

[5] Facts specific to Dr. Fleming's background and qualifications are set forth in Dr. Fleming's expert report which was provided to the Court for consideration as part of the motions to disqualify, and is maintained under seal on the docket. (Doc. No. 942-2.)

II. LEGAL STANDARD

Courts have inherent power to disqualify an expert witness to protect the integrity of the adversary process, protect privileges that otherwise may be breached, and promote public confidence in the legal system. *See Campbell Indus. v. M/V Gemini*, 619 F.2d 24, 27 (9th Cir. 1980). Disqualification, however, is a drastic measure that should be rarely employed after evaluating several considerations. *Hewlett Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1092 (N.D. Cal. 2004). While courts have not established a bright-line rule to determine whether an expert should be disqualified, general principles provide guidance in making such a determination. *Id.* In determining whether disqualification is warranted, courts also balance competing policy objectives as well as fairness and potential prejudice to each party in the litigation. *Id.* at 1093.

III. DISCUSSION

A. Timeliness of Motions to Disqualify

Plaintiffs argue that Defendants' motions to disqualify are untimely and that Defendants waived any objection to Dr. Fleming by not immediately moving to disqualify him after receipt of his designation as an expert for Plaintiffs. (Doc. No. 937, p. 20-22.) Having already considered the parties' arguments on this point, at the hearing on this matter the Court ruled Defendants' motions were timely. Accordingly, as set forth more fully on the record, Defendants' motions are timely and Defendants' arguments regarding disqualification have not been waived. (*See* Doc. No. 1000, p. 5:6-14.)

B. Disqualification Based on a Prior Relationship

Novo moves independently to disqualify Dr. Fleming based on his prior consulting relationship with Novo. When disqualification of an expert is sought based on a prior relationship with an adversary, courts employ a two-pronged inquiry. *Hewlett Packard Co.*, 330 F. Supp. 2d at 1093. Disqualification is generally warranted if (1) the adversary had a confidential relationship with the expert and (2) the adversary disclosed confidential information to the expert that is relevant to the current litigation. *Id.* The party seeking disqualification bears the burden of establishing that both elements of the

disqualification test have been established. *Stencel v. Fairchild Corp.*, 174 F. Supp. 2d 1080, 1083 (C.D. Cal. 2001); *Hewlett Packard Co.*, 330 F. Supp. 2d at 1093 ("[I]f only one of the two factors is present, disqualification likely is inappropriate."). In addition to these two factors, courts also consider whether disqualification would be fair to the affected party and would promote the integrity of the legal process. *Hewlett Packard Co.*, 330 F. Supp. 2d at 1093.

1. Whether Novo Had a Confidential Relationship With Dr. Fleming

The party seeking disqualification of an expert witness must demonstrate that it was objectively reasonable for it to believe a confidential relationship existed with the expert. *Id.* at 1093; *Stencel*, 174 F. Supp. 2d at 1083. The existence or absence of a contract between the parties is not determinative. *Stencel*, 174 F. Supp. 2d at 1083. In evaluating the reasonableness of a party's assumption, courts consider several factors including:

> whether the relationship was one of long standing and involved frequent contacts instead of a single interaction with the expert, whether the expert is to be called as a witness in the underlying case, whether alleged confidential communications were from expert to party or vice-versa, and whether the moving party funded or directed the formation of the opinion to be offered at trial.

Id. Additionally, other factors that may weigh either for or against disqualification include:

> whether the parties entered into a formal confidentiality agreement, whether the expert was retained to assist in the litigation, the number of meetings between the expert and the attorneys, whether work product was discussed or documents were provided to the expert, whether the expert was paid a fee, whether the expert was asked to agree not to discuss the case with the opposing parties or counsel, and whether the expert derived any of his specific ideas from work done under the direction of the retaining party.

Hewlett-Packard, 330 F. Supp. 2d at 1093. The emphasis in evaluating whether a confidential relationship existed "is not on whether the expert was retained per se but whether there was a relationship that would permit the litigant reasonably to expect that any communications would be maintained in confidence." *Twin City Fire Ins. Co. v. Mitsubishi Motors Credit of Am., Inc.*, No.040043, 2006 WL 5164249, at *3 (C.D. Cal. Nov. 6, 2006).

Upon consideration of the above factors and the facts as presented by the parties' briefing and oral argument, the Court finds it was reasonable for Novo to believe its relationship with Dr. Fleming was confidential. Dr. Fleming had a longstanding consulting relationship with Novo which lasted nearly a decade and involved multiple confidentiality agreements. (*See* Doc. No. 902-1, Ex. 2-8.) Plaintiffs do not challenge the existence of the agreements, or the length of Dr. Fleming's relationship with Novo. Instead, Plaintiffs argue the confidentiality agreements alone are insufficient to demonstrate an objectively reasonable expectation of confidentiality. (Doc. No. 937, p. 9.) Additionally, as raised at oral argument, Plaintiffs argue that each of the confidentiality agreements "sunset" or end after a period of years thereby releasing Dr. Fleming from a duty of confidentiality.[6] (Doc. No. 1000, p. 30–33.) Plaintiffs also argue that the factors considered for this prong of the disqualification analysis relate to litigation, and that disqualification is generally only warranted when the expert was consulted for litigation- related purposes. (Doc. No. 937, p. 9.)

Although a presumption of a confidential relationship may not have attached to the relationship between Novo and Dr. Fleming, several considerations support the conclu-

[6] The "sunset" argument was first raised at oral argument and addressed by counsel for both Plaintiffs and Novo. (Doc. No. 1000, p. 30-33.) However, the term of confidentiality imposed by each agreement is not dispositive to the Court's analysis as the relevant inquiry is whether at the time of the disclosure, it was objectively reasonable for Novo to anticipate that its relationship with Dr. Fleming was confidential. *See Life Tech. Corp. v. Biosearch Technologies, Inc.*, No.C-12-00852, 2012 WL 1604710, at *6, n.2 (N.D. Cal. May 7, 2012) ("The one-year lapse in time here, however, is not relevant in determining whether Life Tech was reasonable in believing it had a confidential relationship with [the expert] at the time he was consulting for Life Tech."). Further, as set forth above, the existence of confidentiality agreements does not end the inquiry for this element, and the Court's conclusion does not rest on this fact alone.

sion it was objectively reasonable for Novo to believe it had a confidential relationship with Dr. Fleming. Not only did Novo require Dr. Fleming to enter into confidentiality agreements throughout the course of his consulting work, Dr. Fleming worked with Novo over a prolonged period of time and regarding a variety of information. While the amount of information Novo provided to Dr. Fleming to facilitate his consulting work is of dispute,[7] it is unlikely that "so little of substance ocurr[ed] during the course of the relationship" such that an expectation of confidentiality between Novo and Dr. Fleming did not attach. *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1094 (quoting *Paul By & Through Paul v. Rawlings Sporting Goods Co.*, 123 F.R.D. 271, 278 (S.D. Ohio 1988) ("[T]here may be situations where, despite the existence of a formal contractual relationship, so little of substance occurs during the course of the relationship that neither the integrity of the trial process, nor the interests of the party who retained the expert, would be served by blanket disqualification.").

The breadth of Dr. Fleming's consulting work, the duration of the relationship, and the existence of seven consulting agreements designed to establish a confidential consulting relationship warrant finding this prong of the disqualification inquiry satisfied. *See Oracle Corp. v. Drug Logic, Inc.*, No. C-11-00910, 2012 WL 2244305, at *6 (N.D. Cal. June 15, 2012) ("Here, Dr. Nelson had a consulting relationship with Relsys that spanned many years and in the course of that relationship signed two confidentiality agreements, as well as the Settlement Agreement containing a confidentiality provision. Therefore, Oracle has satisfied the first part of the test."); *Cf.*, *Ziptronix, Inc. v. Omnivision Tech., Inc.*, No. C-10-05525, 2013 WL 146413, at *2 (N.D. Cal. Jan. 14, 2013) (no finding of a confidential relationship despite non-disclosure agreement because "after signing the NDA, Plaintiff never gave [the expert] any confidential information, never gave [the expert] any consulting work, and did not tell [the expert] what patents

[7] Plaintiffs argue that the majority of information exchanged between Novo and Dr. Fleming involved Dr. Fleming and other advisors providing confidential information to Novo. (Doc. No. 937, p. 10.) The Court finds it unlikely that Dr. Fleming was able to form opinions and provide drug-specific analyses without information from Novo.

were at issue"). Further, not all of the factors that courts consider relate directly to litigation strategy, and the Court is convinced the facts of this case warrant a finding of a confidential relationship even absent discussion of litigation between Novo and Dr. Fleming. Accordingly, Novo has met its burden as to the first prong of the disqualification analysis.

2. Whether Novo Disclosed Confidential Information Relevant to The Litigation

The second consideration in whether to disqualify an expert due to a prior relationship is whether confidential information relevant to the litigation was disclosed to the expert during the confidential relationship. *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1093. Confidential information is information which is "of either particular significance or [that] which can be readily identified as either attorney work product or within the scope of the attorney-client privilege." *Id.*; *Paul By & Through Paul*, 123 F.R.D. at 279. "Unlike attorney-client communications, discussions between parties or counsel and experts do not carry the presumption that confidential information was exchanged." *Stencel*, 174 F. Supp. 2d at 1083. The party seeking to disqualify an expert must point to specific and unambiguous disclosures that if revealed would prejudice the party. *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1094; *Life Technologies Corp.*, 2012 WL 1604710, at *7. Confidential information can also include discussion of the party's "strategy in the litigation, the kinds of experts [the party] expected to retain, [the party's] view of the strengths and weaknesses of each side, the role of each of the [party's] experts to be hired and anticipated defenses." *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1094.

Novo argues that the documents Dr. Fleming relied on in forming his expert report relate to the topics Dr. Fleming had confidential communications with Novo about, or otherwise stemmed from information obtained during his consulting relationship with Novo. (Doc. No. 925, p. 19.) Plaintiffs argue that the information obtained by Dr. Fleming was purely technical, unrelated to the instant litigation, and did not involve information that constitutes attorney work product or that is subject to attorney-client

privilege. (Doc. No. 937, p. 14-16.) Plaintiffs contend that since Dr. Fleming's consulting was unrelated to litigation, he was not privy to litigation strategy, never spoke with any attorneys and was not paid to form any opinions,[8] the information is not confidential. (*Id.* at 16-17.)

While at least one court has concluded that "[c]ommunication based upon technical information as opposed to legal advice is not considered privileged," *Nikkal Indus., Ltd. v. Salton, Inc.*, 689 F. Supp. 187, 191–92 (S.D.N.Y.1988), other courts have looked at whether the technical information underlying the consulting relationship is the same information at issue in the litigation. *See e.g. Pellerin v. Honeywell Int'l Inc.*, No. 11CV1278, 2012 WL 112539, at *3 n.1 (S.D. Cal. Jan. 12, 2012) (finding information relevant to the litigation where "the technical information is confidential, propriety information obtained in the course of employment for the disclosing party, subject to a non-disclosure agreement"); *Oracle Corp.*, 2012 WL 2244305, at *7 ("[T]he record as a whole supports Oracle's contention that Dr. Nelson had access to confidential information about the accused technology—at least as to the accused Relsys products—and even played a role in developing it."); *Cf. Novartis AG v. Apotex Inc.*, No. 09-5614, 2011 WL 691594 (D.N.J. Jan. 24, 2011)[9] ("Moreover, Apotex has not demonstrated how Dr. Klibanov's general knowledge of Apotex's regulatory practices relates to the technology at issue in this case.").

---

[8] Plaintiffs also argue that during the last five years of his consulting relationship with Novo, Dr. Fleming received a yearly payment of "at most $6,000 plus expenses." (Doc. No. 937, p. 6.) Although this is a factor court's consider in whether a party had a reasonable expectation of a confidential relationship, the appropriate inquiry is whether the substance of interactions between an expert and the adversary was such that an expectation of confidentiality attached. *See Life Tech. Corp.*, 2012 WL 1604710, at *6. Thus, while the Court notes that Dr. Fleming may have received a fairly modest payment for his work during the last five years of his consulting relationship, this fact does not significantly weigh against a finding that Novo was reasonable in expecting its relationship with Dr. Fleming was confidential or that confidential information relevant to the litigation was disclosed to Dr. Fleming.

[9] *Report and recommendation adopted*, No. CIV.A. 09-c-5614, 2011 WL 611706 (D.N.J. Feb. 8, 2011).

Although Dr. Fleming's consulting relationship may have predated the instant litigation, several considerations weigh against the arguments asserted by Plaintiffs. Perhaps the most compelling is that Dr. Fleming's work with Novo related to Victoza. Specifically, Dr. Fleming had access to clinical data, research, and regulatory submissions such as the NDA, and IND applications for Victoza, all of which could be of "particular significance" to this litigation. *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1094 (quoting *Paul By & Through Paul*, 123 F.R.D. at 279). Thus, not only did Dr. Fleming's work involve the same drug at issue in this litigation, he consulted on issues relevant to Plaintiffs' claims such as Victoza clinical data.

Plaintiffs highlight the lapse of time between Dr. Fleming's consulting work and the underlying litigation to argue any information Dr. Fleming obtained related to Victoza is now outdated or irrelevant. (Doc. No. 937, p. 17.) Plaintiffs cite to *Lyman v. Pfizer* to support their argument that any information Dr. Fleming received is out of date as related to the current litigation. In *Lyman*, the court relied on a four-year gap between the time the expert had worked for the defendants and the litigation at issue as a factor weighing against disqualification. *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2011 WL 3843956, at *4 (D. Vt. Aug. 30, 2011). *Lyman* is distinguishable from the instant matter because although Dr. Fleming's work with Novo began in 1999, Plaintiffs have sought and received discovery from Novo dating back to as early as 2002. (*See* Doc. No. 1000, p. 9:5-23.) As Novo notes, Plaintiffs should not be allowed to argue the temporal gap between this litigation and Dr. Fleming's work with Novo makes information obtained by Dr. Fleming currently irrelevant or outdated. Further, even if the particular data regarding Victoza that Dr. Fleming was privy to is now outdated, Novo's internal practices, policies, and strategies remain valuable information unobtainable by other experts. Plaintiffs also argue that information regarding regulatory strategy does not qualify as confidential information and cite to *Novartis AG v. Apotex Inc.*, in support of this proposition. (Doc. No. 937, p. 13.) While general regulatory strategy may be insufficient

to meet this prong of the disqualification analysis, Dr. Fleming was privy to regulatory strategy specific to Victoza.

Plaintiffs next argue that the information obtained by Dr. Fleming is not confidential because all of the information is either publicly available through the FDA's September 11, 2014, briefing document regarding liraglutide (Victoza), or through discovery. (*Id.* at 16.) Some courts consider whether the confidential information that is disclosed to the expert is nevertheless discoverable by the opposing party as weighing against disqualification. *See Twin City Fire Ins. Co.*, 2006 WL 5164249, at *4 ("Only the disclosure of confidential information that the opposing party would be unable to obtain through discovery should form a basis for disqualification of an expert witness."). Novo does not concede that all of the information Dr. Fleming obtained is discoverable. Instead, Novo argues it would be impossible for Dr. Fleming to differentiate between information he obtained through his confidential consulting relationship with information otherwise obtained through discovery or outside sources. (Doc. No. 937, p. 8.) Novo notes that Dr. Fleming not only had access to Novo documents and materials, but also has mental impressions from interactions with Novo executives, as well as his recollection of private conversations and discussions that are inherently part of his conscious knowledge regarding Victoza. (Doc. No. 949, p. 8.)

The Court finds Novo's argument persuasive. Not only was Dr. Fleming given material relevant to Victoza which Novo intended to remain confidential, he was also present at a variety of meetings, presentations, and other events wherein confidential material was shared. Dr. Fleming's presence and role as a consultant for Novo placed him in a position that an unrelated preemption expert would not share. Dr. Fleming was subject to information regarding internal practices, clinical data, and regulatory submissions, all of which are topics discussed by Dr. Fleming in his expert report. While some of Dr. Fleming's report includes information obtained through Dr. Fleming's work with the FDA, much of the report overlaps significantly with information related to Victoza. Only some of the information obtained by Dr. Fleming would be exchanged through the

course of discovery and available to any expert. Dr. Fleming's mental impressions, the mental impressions of others who worked for Novo, either as internal players or other consultants, as well as strategy discussions are incapable of memorialization via meeting minutes or summaries of events and would not be discoverable information.

Moreover, it is unlikely that the information Dr. Fleming obtained through his consulting work can be maintained in confidence given that it overlaps significantly with the information at issue in this litigation. *See Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, No. 11CV2214, 2013 WL 3367575, at *5 (S.D. Cal. July 5, 2013) ("[T]he risk of inadvertent disclosure does not arise solely from an information recipient's level of influence within an entity, but rather, from being in a position where the subtle percolation of the confidential information can tangibly and unavoidably alter the recipient's actions.") (internal citations omitted); *Pellerin*, 2012 WL 112539, at *3 ("There is a substantial risk [the expert] may inadvertently use confidential information he is contractually barred from disclosing to Pellerin in his role as expert . . . the human brain does not compartmentalize information in that manner."). For these reasons, Dr. Fleming's declaration in opposition to disqualification is less persuasive.[10]

Plaintiffs' final argument that Novo cannot point to specific and unambiguous disclosures to Dr. Fleming that would be prejudicial if disclosed is initially compelling. As part of its burden in seeking disqualification, Novo must identify specific information and disclosures to Dr. Fleming. This, however, presupposes that Dr. Fleming's role, and the information he received can be entirely documented by meeting minutes, agendas, and other discoverable information. The scope of Dr. Fleming's involvement, as evi-

[10] Dr. Fleming's declaration states that he cannot think of how information obtained in connection with his consulting work for Novo would be useful in the context of his expert report. (Doc. No. 937-1, p. 2.) However, because Dr. Fleming's consulting work related to Victoza, a concern is that Dr. Fleming would be unable to distinguish between information obtained while working for Novo from the information obtained in the course of discovery. This is particularly true with respect to information incapable of complete representation in discoverable documents such as mental impressions and conversations between Dr. Fleming, other experts, and Novo executives.

denced from the consulting agreements and the key meetings listed by Novo, even if qualified by Plaintiffs' representations, demonstrates Dr. Fleming's role as a key player in key moments of Victoza's development and regulatory approval process.

Thus, the Court finds that Novo disclosed confidential information relevant to the litigation to Dr. Fleming and disqualification is warranted. However, the Court is mindful of policy considerations that weigh for and against disqualification and aid the Court in fashioning an appropriate outcome.

3. Fairness and Policy Considerations

In considering disqualification, courts also consider fairness, and whether any prejudice might occur if an expert is or is not disqualified. *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1095; *Stencel*, 174 F. Supp. 2d at 1083. Additional policy considerations include allowing experts to pursue their trade and permitting parties to select their own experts. If experts are permitted to breach confidentiality agreements, they might be motivated "to sell their opinions to the opposing parties or the highest bidder without concern about the potential confidentiality of their previous consultations." *Hewlett-Packard Co.*, 330 F. Supp. 2d at 1095 (internal citations omitted). Similarly, a retaining party might be motivated "not to withdraw a previously designated expert while litigation is pending for fear that the party's confidential information would become available to its adversary." *Id.* However, "if experts are too easily disqualified, unscrupulous attorneys may attempt to create relationships with numerous potential experts at a nominal fee hoping to preempt the ability of their adversaries to obtain expert assistance." *Id.*

Both parties invoke these policy considerations in support and opposition of disqualification. Plaintiffs have recognized that other potential experts could be retained in place of Dr. Fleming, particularly with respect to future designations of experts on general and specific causation, as well as endocrinology. (Doc. No. 1000, p. 22:7-17.) Plaintiffs have also argued, however, that a grant of disqualification could lead to widespread disqualification based on any type of prior relationship. (Doc. No. 937, p. 25;

Doc. No. 1000, p. 20:10-18.) The Court is unconvinced that disqualification in this case would support disqualification based on a singular interaction between an expert and an adversary, thereby allowing parties to preempt use of an expert by an opponent. To the contrary, when experts enter into consulting agreements governed by confidentiality provisions, policy considerations support upholding the agreements, particularly in instances where the consulting relationship substantially overlaps the expert opinion later offered against that party. While court's should take into consideration an expert's ability to pursue his trade, particularly in a narrow or specialized field, disqualification does not prevent Dr. Fleming from working as an expert. It is Dr. Fleming's affiliation to Victoza in differing capacities—as confidential advisor to Novo and as expert to Plaintiffs—that the Court finds problematic. *See Rupp v. United States*, No. 06cv0515, 2008 WL 4279408, at *4 (S.D. Cal Sept. 16, 2008)[11] (noting that an expert could be given an unfair advantage to the plaintiff's disadvantage if he were able to present himself at trial as one of the plaintiff's physicians and as the defendant's expert). Thus, the fairness and policy considerations support disqualification based on Dr. Fleming's prior relationship. Before addressing the appropriate remedy, the Court will consider the alternate grounds asserted for disqualification.

C. Disqualification Based on Violation of the Protective Order

As an independent basis for disqualification, all Defendants argue that Plaintiffs violated the protective order by not providing notice to Defendants prior to the disclosure of confidential information to Dr. Fleming. (Doc. No. 925, p. 23-25; Doc. No. 908-1.) According to Defendants, Dr. Fleming constitutes a "competitor" within the terms of the protective order and Plaintiffs were required to notify Defendants fourteen (14) days prior to the disclosure of confidential information. (Doc. No. 908-1, p. 3; Doc. No. 925, p. 24.) The protective order provides:

---

[11] Affirmed in part, and vacated as to additional considerations placed on the expert's work as an expert witness by *Rupp v. U.S.*, (2008) WL 6638217 (S.D. Cal. Nov. 26, 2008).

> Before disclosing confidential discovery materials to any person listed in 5(a)(1) or 5(a)(6)-(8) who is a customer or competitor (or an employee of either) of the producing party or the person or entity on whose behalf the producing party designated the materials as "Confidential," the party wishing to make such disclosures shall give at least fourteen (14) days advance notice in writing to the counsel who designated such information as confidential stating that such disclosure will be made and identifying with particularity the Confidential Discovery Materials to be disclosed and stating the purpose for disclosure. (Doc. No. 564, p. 9.)

The protective order defines a "competitor" as "any manufacturer or seller of prescription medications other than producing party, including without limit other defendants." (*Id.*)

Defendants argue that Dr. Fleming is a "competitor" as defined by the protective order because he is the Co-Founder, Chairman, and Chief Medical Officer of Exsulin. (Doc. No. 925, p. 24-25; Doc. No. 908-1, p. 3-4.) Defendants contend that the word "manufacturer" as traditionally defined and understood, encompasses Exsulin and Dr. Fleming, particularly as Exsulin is developing a drug similar to the drugs manufactured by Defendants.

Plaintiffs argue that Dr. Fleming is not a competitor because he is not employed by a manufacturer or seller of prescription medication. (Doc. No. 937, p. 18.) Plaintiffs contend that Exsulin does not manufacture or sell prescription medications, and instead Exsulin is a "drug development" company. (*Id.*)[12] Plaintiffs also argue that if Defendants intended the protective order to include companies such as Exsulin, Defendants could have accounted for that in creating the protective order adopted in this matter. (*Id.* at 19.) Finally, Plaintiffs contend that the protective order is not ambiguous, but to the extent that it is, the term manufacturer should be interpreted in light of federal law as embodied in the FDCA. (*Id.*)

[12] Dr. Fleming's declaration also states that Exsulin does not manufacture or sell any FDA-approved prescription medication. (Doc. No. 937-1, p. 5.)

A protective order should be read in a reasonable and common sense manner so that its prohibitions are connected to its purpose. *In re Dual Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d 693, 695 (9th Cir. 1993); *Great W. Life & Annuity Ins. Co. v. Am. Econ. Ins. Co.*, No. 2:11CV02082, 2013 WL 5332410, at *5 (D. Nev. Sept. 23, 2013) ("[A] protective order based on a written agreement between the parties is subject to the rules of contractual interpretation, including that the agreement should be enforced in accordance with the ordinary meaning of the language used in the agreement."). The parties do not dispute that information properly designated as confidential by each Defendant was exchanged through the course of discovery and given to Dr. Fleming by Plaintiffs. Plaintiffs acknowledge that Dr. Fleming signed the endorsement of the protective order as required by third parties receiving confidential materials. (Doc. No. 937, p. 6.)[13] The issue, therefore, is not whether the information was properly designated as confidential, but whether Dr. Fleming is a competitor as defined by the protective order.

The plain language of the protective order supports the conclusion that Dr. Fleming is a competitor. Plaintiffs' argument distinguishing between a manufacturer and a developer presumes a meaningful difference in the context of the protective order. That Exsulin is not currently selling its prescription medication does not exempt the company from the definition of a competitor given the disjunctive definition provided in the protective order. (*See* Doc. No. 564, p. 9, defining a competitor as "any manufacturer or seller of prescription medications"). Additionally, Exsulin is currently engaged in clinical trials of its peptide-based drug which supports the conclusion that the company has manufactured the drug that is the subject of the trials.

Plaintiffs note that Exsulin is not registered as a manufacturer with the FDA, and thus argue that Exsulin does not fall within the terms of the protective order. (Doc. No.

[13] Additionally, in considering many of the relevant documents attached to the instant motions, the Court found good cause to seal the documents to maintain confidentiality. (*See* Doc. Nos. 924, 941, 955.)

937, p. 7.) However, the protective order does not specify that a "competitor" is a manufacturer that is registered with the FDA or a manufacturer as defined by the FDA. Use of the word manufacturer without further modifications (i.e. "manufacturer as defined by the FDA," or "manufacturer of FDA approved pharmaceuticals") suggests that the parties intended the word to be used as it is ordinarily understood. As such, resort to extrinsic definitions is unnecessary. *See e.g.*, *United States v. McCaleb*, 552 F.3d 1053, 1059 (9th Cir. 2009) (concluding district court did not plainly err by using but not defining the term "manufacture" because "it is a common word which an average juror can understand and which the average juror could have applied to the facts of [the] case without difficulty"). Under the clear language of the protective order, Exsulin is a competitor because it is engaged in the manufacture of a prescription drug, and the Court is satisfied that Exsulin, and thus by extension Dr. Fleming, is therefore engaged in competitive conduct. Accordingly, Plaintiffs were required to give notice to Defendants prior to the disclosure of confidential discovery materials.

Finally, Plaintiffs also argue that any confidential discovery materials given to Dr. Fleming were redacted and did not include information beneficial to a competitor such as trade secrets. (Doc. No. 937, p. 23; Doc. No. 1000, p. 47:3-11.) Similarly, Plaintiffs argue that Defendants cannot establish they were prejudiced in Plaintiffs' failure to give notice. Defendants have no obligation to make such a showing. Strict compliance with the terms of the protective order is anticipated, and required in cases such as this where multiple market competitors are engaged in litigation. The harm to Defendants occurred when Plaintiffs failed to give notice as contemplated by the protective order. If notice had been given to Defendants, the issue of whether Dr. Fleming was a competitor could have been addressed proactively, thereby preventing improper disclosure. Plaintiffs deprived Defendants of this opportunity by not giving notice, or at the very least, anticipating the competitor argument would be raised given Dr. Fleming's role at Exsulin and Exsulin's role in the production, development, and manufacture of its peptide-based drug.

As such, the Court concludes that Plaintiffs violated the protective order by not providing notice to Defendants prior to the disclosure of confidential discovery materials to Dr. Fleming.

D. Appropriate Remedy

Based on both Dr. Fleming's prior consulting relationship, as well as Plaintiffs violation of the protective order, disqualification of Dr. Fleming is warranted. At the hearing on this matter, the parties addressed potential remedies both in relation to Novo's separate motion seeking disqualification, and Plaintiffs violation of the protective order. In formulating the remedy set forth below, the Court is guided by several policy considerations, as well the practical implications of disqualification. The Court has aimed to cure the issues raised by Defendants' motions while not unreasonably delaying the litigation, prejudicing Plaintiffs, or inhibiting Dr. Fleming's ability to pursue his profession despite his prior work for Novo.

With respect to Novo's motion, the Court finds disqualification of Dr. Fleming warranted as to information in his report related to his prior consulting relationship. Dr. Fleming's prior experience and expertise as related to FDA regulatory practices, however, was undoubtedly obtained independent of Dr. Fleming's consulting work for Novo. Thus, Dr. Fleming is permitted to remain as Plaintiffs' preemption expert, but his report must be similarly limited. Dr. Fleming is disqualified from serving as an expert for Plaintiffs on issues of general causation, specific causation, and endocrinology. For the purpose of future motions, and other proceedings in this case, the Court will only consider the following portions of Dr. Fleming's expert report: Sections I (Qualifications and Credentials), II (Introduction), IV (Manufacturer Responsibility for Drug Safety and Adequacy of the Label), V (FDA Approval Process), VII (Label Change by CBE), and VIII (FDA Process Requiring Label Change), XI (Section A regarding FDA Opposition to Pancreatic Cancer Warnings, pages 89-90) and (Section A(2)(a) and (b) regarding Addition of Pancreatic Cancer Warning, pages 101-107).

///

The Court finds the remaining sections of Dr. Fleming's expert report overlap with information that Dr. Fleming was privy to while working as a confidential consultant for Novo, and those sections will not be considered by the Court. To prevent delay or further dispute as to Dr. Fleming's report, Plaintiffs are not required to file a separate partial or redacted version of Dr. Fleming's report. The Court has tasked itself with parsing the relevant FDA preemption information from the report as it is currently drafted. This will prevent Plaintiffs from having to find a new expert regarding FDA regulations, and permit the parties to immediately move forward to retain further experts as necessary in relation to the anticipated procedure of this case.

With respect to Defendants' motion to disqualify Dr. Fleming based on the violation of the protective order, the Court finds disqualification is similarly warranted. The protective order authorizes the imposition of sanctions in instances of intentional violation, (Doc. No. 564, p. 16), and Rule 37 grants courts wide discretion in fashioning remedies for violations of discovery orders such as the protective order. *See* Fed. R. Civ. P. 37(b). Limiting Dr. Fleming's expert report as set forth above operates to cure violation of the protective order by preventing consideration of Dr. Fleming's drug-specific opinions derived from the disclosure of confidential materials. By so limiting Dr. Fleming's expert report, the Court upholds the terms of the protective order and encourages strict compliance with court orders in the future.

V. CONCLUSION

As set forth more fully above, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' motions to disqualify Dr. Fleming and strike his expert report. The parties are directed to meet and confer as to a potential time line for preemption-based motions in preparation for the April 2, 2015, telephonic status conference.

IT IS SO ORDERED.

DATED: April 1, 2015

Hon. Anthony J. Battaglia
U.S. District Judge